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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,026	10/30/2003	Jeffrey A. Hall	279.401US1	7128
21186	7590	03/31/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/698,026	HALL ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☒ Claim(s) 18 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/13/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on February 8, 2006. All prior objections and rejections are withdrawn in view of the amended claims.

Claim Objections

Claim 18 is objected to because of the following informalities: "the platinum tip electrode" lacks antecedent basis in claim 16. Appropriate correction is required.

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 16 already claims "at least one of the electrodes including a tip electrode".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 17, and 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sherman (U.S. Pat. No. 6,059,778).

Regarding claim 16, Sherman discloses a system for delivering RF energy to an endocardial tissue, the system comprising:

a catheter 30 having one or more electrodes 32, 36 proximate a distal end of the catheter, the catheter adapted for being positioned such that the one or more electrodes are adjacent the endocardial tissue (Fig. 1), at least one of the electrodes including a tip electrode 36; and

a power control system 20 to provide power to the tip electrode (inherently capable of this intended use), the power having a plurality of alternating on portions and off portions, one set of adjacent on and off portions defining a duty cycle (col. 3, ln. 37-38 and col. 7, ln. 41-43, 63-67);

wherein the power control system delivers an energy pulse of between approximately 0.01 ms to 4 ms (col. 7, ln. 44-52), and the on portions and off portions of the duty cycle have a ratio of between 50% - 100% (col. 7, ln. 44-52).

The claim further calls for the tip electrode to have a thermal time constant of approximately 240 ms. Since the ring electrodes 32 of Sherman comprise platinum (col. 6, ln. 36-41), it would be obvious, if not inherent, to have the tip electrode 36 also comprise platinum. Sherman further discloses that the tip electrode has a diameter of 2.3 mm, which is equal to 0.091 inches (col. 6, ln. 52-53). Since the tip electrode of Sherman comprises platinum and practically has the exact same diameter (0.091

inches vs. 0.094 inches) as the platinum tip of applicant's device, it would be obvious, if not inherent, for the electrode tip of Sherman to have a thermal time constant of approximately 240 ms.

Furthermore, applicant has not disclosed any criticality or unexpected result associated with having a thermal time constant of approximately 240 ms, since applicant discloses that the claimed system applies to "almost any electrode for RF ablation" (specification pg. 8, ln. 10-11).

Regarding claim 17, Sherman discloses the system of claim 16, wherein the duty cycle chosen ranges from 80% to 100%. The device of Sherman is inherently capable of operating at a duty cycle of 80% to 100%. In addition, applicant has not disclosed any criticality or unexpected result associated with this limitation.

Regarding claim 19, Sherman discloses the system of claim 16, wherein the RF energy has a period of between 120 ms and 240 ms. The device of Sherman is inherently capable of operating as claimed. In addition, applicant has not disclosed any criticality or unexpected result associated with this limitation.

Regarding claim 20, Sherman discloses the system of claim 16, wherein the RF energy has a period of greater than 240 ms. The device of Sherman is inherently capable of operating as claimed. In addition, applicant has not disclosed any criticality or unexpected result associated with this limitation.

Regarding claim 21, Sherman discloses the system of claim 16, wherein one of the one or more electrodes includes a tip electrode 36 (Fig. 1).

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Regarding claim 22, Sherman discloses the system of claim 16, wherein one of the one or more electrodes includes a ring electrode 32 (Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman ('778).

Regarding claim 18, Sherman discloses the system of claim 16. Sherman, however, does not expressly disclose that the platinum tip electrode includes an approximately 5 mm tip with a diameter of approximately 0.094 inches.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the platinum tip electrode

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of Sherman have an approximately 5 mm tip with a diameter of approximately 0.094 inches because applicant has not disclosed that making the platinum tip electrode to include an approximately 5 mm tip with a diameter of approximately 0.094 inches provides an advantage, is used in a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either the approximate dimensions of Sherman or the claimed approximate dimensions because on page 8, lines 10-11 of the specification, applicant states that the present system applies to almost any electrode for RF ablation.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman ('778) in view of Sherman (U.S. Pat. No. 5,971,980).

Regarding claim 23, Sherman ('778) discloses a method of RF ablation comprising:

delivering RF energy to a tissue from an electrode 32 having a thermal constant of approximately 240 ms (see the preceding rejection of claim 1);

controlling the RF energy such that the RF energy is delivered in an energy pulse of between approximately 0.01 ms to 4 ms (col. 7, ln. 44-52), and a duty cycle having a ratio of between 50% - 100% (col. 7, ln. 44-52).

The claim differs from Sherman ('778) in calling for delivering RF energy specifically from a tip electrode. Sherman ('778) discloses a tip electrode 36 (col. 6, ln. 19-20 and Fig. 1) but does not expressly disclose that it delivers RF energy. Sherman ('980), however, discloses an analogous ablation probe comprising a ring electrode 26

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and a tip electrode 22, which both deliver RF energy to tissue (col. 4, ln. 1-10 and Figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have delivered RF energy from the tip electrode of Sherman ('788) in view of the teaching of Sherman ('980) as an obvious way of using a tip electrode that is well-known in the art.

Regarding claim 24, Sherman ('788) discloses the method claim 23 in view of Sherman ('980). In addition, at the time the invention was made, it would have required only routine skill in the art to have made the RF energy period between 120 ms and 240 ms or any desired time period. Furthermore, applicant has not disclosed any criticality or unexpected result associated with this specific range.

Regarding claim 25, Sherman ('788) discloses the method claim 23 in view of Sherman ('980). Sherman ('980) further discloses operating the device with a duty cycle in the range of 80% to 100% (col. 8, ln. 31-44) to create a shallower ablation lesion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the duty cycle of Sherman ('788) in the range of 80% to 100% in view of the teaching of Sherman ('980) in order to create a shallower lesion. In addition, applicant has not disclosed any criticality or unexpected result associated with this limitation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

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US 4903696 A	USPAT	Stasz; Peter et al.
US 4907589 A	USPAT	Cosman; Eric R.
US 5573533 A	USPAT	Strul; Bruno
US 5643287 A	USPAT	Ahad; Sam J.
US 6053912 A	USPAT	Panescu; Dorin et al.
US 6117131 A	USPAT	Taylor; Junius E.
US 6293943 B1	USPAT	Panescu; Dorin et al.
US 6306134 B1	USPAT	Goble; Nigel Mark et al.
US 20020058933 A1	US-PGPUB	Christopherson, Mark A. et al.
US 6391026 B1	USPAT	Hung; David et al.
US 6428537 B1	USPAT	Swanson; David K. et al.
US 20040030329 A1	US-PGPUB	Hagg, Martin

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

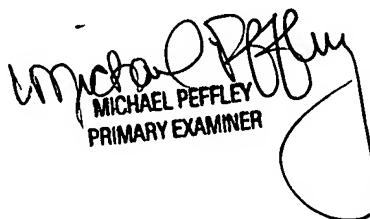
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
3/24/06


MICHAEL PEFFLEY
PRIMARY EXAMINER